John J. Francis, Jr. (JF 1655)
DRINKER BIDDLE & SHANLEY LLP
500 Campus Drive
Florham Park, New Jersey 07932
(973) 360-1100
Attorneys for Plaintiff
Warner-Lambert Company and
Gödecke Aktiengesellschaft

Of Counsel:
Robert L. Baechtold (RB 6866)
Hugh C. Barrett (HB 8146)
FITZPATRICK, CELLA, HARPER
& SCINTO
30 Rockefeller Plaza
New York, New York 10112



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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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| WARNER-LAMBERT COMPANY and GÖDECKE AKTIENGESELLSCHAFT | : | |
| Plaintiffs, | : | Civil Action No. 00-2931 (FCL) |
| v. | : | |
| PUREPAC PHARMACEUTICAL CO. and FAULDING INC. | : | |
| Defendants. | : | |

## COMPLAINT

For their complaint herein, Plaintiffs allege as follows:

**THE PARTIES**

1. Plaintiff Warner-Lambert Company is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 201 Tabor Road, Morris Plains, New Jersey 07950.

2. Plaintiff Gödecke Aktiengesellschaft is a corporation incorporated under the laws of Germany, having its principal place of business in Berlin, Germany.

3. Gödecke Aktiengesellschaft is an indirect wholly owned subsidiary of Warner-Lambert Company and together they are hereinafter referred to as "Warner-Lambert".

4. On information and belief, Defendant Purepac Pharmaceutical Co. ("Purepac") is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

5. On information and belief, Defendant Faulding Inc. ("Faulding") is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

6. On information and belief, Purepac is a wholly owned subsidiary of Faulding and the two have common officers and directors. On information and belief, the acts of Purepac complained of herein were done at the direction of,

with the authorization of and with the cooperation, participation and assistance of Faulding.

## JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America. Jurisdiction is founded on Title 28, United States Code §§ 1331, 1338(a), 2201 and 2202.

8. Because Purepac and Faulding reside in this judicial district, venue is proper in this Court under Title 28, United States Code §§ 1391(b), 1391(c) and 1400(b).

## CLAIMS FOR RELIEF

9. On March 30, 1998, Purepac and Faulding filed Abbreviated New Drug Application ("ANDA") No. 75-350 for gabapentin capsules. On September 3, 1999, Purepac and Faulding filed Abbreviated New Drug Application ("ANDA") No. 75-694 for gabapentin tablets. In those ANDAs Purepac certified to Warner-Lambert's patents then listed in the F.D.A.'s "Orange Book" and Warner-Lambert brought suit in this Court on those certifications.

10. United States Patent No. 6,054,482 (the "'482 patent") discloses and claims pharmaceutical compositions of the drug gabapentin. The '482 patent was duly and legally issued on April 25, 2000 and expires on April 25, 2017. Plaintiff Gödecke Aktiengesellschaft is the assignee of the

'482 patent. A copy of the '482 patent is attached as Exhibit A.

11. Gabapentin under certain conditions converts to a form called the lactam. The lactam presents a toxicity problem and must therefore be avoided in gabapentin compositions. The '482 patent discloses and claims pharmaceutical compositions of gabapentin that are substantially lactam free.

12. On information and belief, the formulation of Purepac's and Faulding's gabapentin capsules and tablets provide for gabapentin compositions that are substantially lactam free and fall within the claims of the '482 patent.

13. Warner-Lambert is the holder of approved New Drug Applications ("NDAs") No. 20-235 for gabapentin capsules and No. 20-882 for gabapentin tablets. On April 25, 2000 Warner-Lambert submitted to the F.D.A. patent information regarding the '482 patent for its NDAs Nos. 20-235 and 20-882 and the F.D.A. has listed the '482 patent in its "Orange Book." Warner-Lambert, through its Parke-Davis Division, sells gabapentin under the tradename "NEURONTIN®."

14. Purepac and Faulding are required by 21 U.S.C. § 355 (j)(2)(A)(vii) and (j)(2)(B) to submit a certification regarding the '482 patent and to provide notice thereof to Warner-Lambert. Specifically, Purepac and Faulding were required either to state that it did not seek approval of

their ANDA for gabapentin capsules prior to the expiration of the '482 patent (a "paragraph III certification") or to state that the '482 patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA was submitted (a "paragraph IV certification").

15. If Purepac and Faulding made a paragraph IV certification, they were required, under 21 U.S.C. § 355(j)(2)(B), to represent to the F.D.A. that they would send a notice of that fact to Warner-Lambert, including a detailed statement of the factual and legal basis of Purepac and Faulding's belief that the '482 Patent is invalid and will not be infringed. Warner-Lambert has not received such a notice. On information and belief, Purepac and Faulding have not sent such a notice.

16. On information and belief, Purepac and Faulding did not make a paragraph III certification, and did not request the F.D.A. to defer any approval of their ANDA for gabapentin capsules until after the expiration of the '482 patent and therefore Purepac and Faulding committed an act of infringement of the '482 patent as provided in 35 U.S.C. § 271(e)(2).

17. Because Purepac and Faulding have not complied with the requirements of 21 U.S.C. § 355(j)(2)(A)(vii) and (j)(2)(B), they do not have a complete, approvable ANDA for gabapentin capsules.

18. Purepac and Faulding have attempted to circumvent the procedure mandated by 21 U.S.C. § 355(j)(2)(A)(vii)(IV) by improperly filing a pre-emptive declaratory judgment action against Warner-Lambert for non-infringement and invalidity of the '482 patent in this Court on April 28, 2000 (Civ. Action No. 00 Civ. 2053 (JCL)).

19. Purepac and Faulding were and are precluded by 21 U.S.C. § 355 (j)(5)(B)(iii) from bringing their declaratory judgment action.

20. Warner-Lambert is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Purepac's and Faulding's gabapentin ANDAs be a date which is not earlier than the April 25, 2017 expiration date of the '482 patent.

21. Warner-Lambert is entitled to an order of this Court compelling Purepac and Faulding to follow the required procedures under 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) and (j)(2)(B)(ii) for submitting a certification on the '482 patent and providing Warner-Lambert with notice of such certification, as well as an order enjoining Purepac and Faulding from pursuing any declaratory judgment action relating to the '482 patent prior to the expiration of the 45-day period after such notice as required under 21 U.S.C. § 355 (j)(5)(B)(iii).

**PRAYER FOR RELIEF**

22. Warner-Lambert requests that:

a. Judgment be entered that Purepac and Faulding have infringed the '482 patent by submitting the aforesaid ANDAs;

b. A permanent injunction be issued pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Purepac and Faulding, their officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, any gabapentin composition covered by the '482 patent;

c. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Purepac's and Faulding's ANDAs be a date which is not earlier than the April 25, 2017 expiration date of the '482 Patent;

d. An injunction be issued restraining and enjoining Purepac and Faulding, their officers, agents, attorneys and employees, and those acting in privity or concert with it, from pursuing their declaratory judgment action before the expiration of 45 days after giving Warner-Lambert notice pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii);

e. An order be issued compelling Purepac and Faulding to follow the appropriate procedures of 21 U.S.C.

§ 355 and to submit a certification with respect to the '482 patent;

f. Judgment be entered for costs and reasonable attorney fees to be awarded to Warner-Lambert; and

g. This Court award such other and further relief as the Court may deem proper under the circumstances.

DRINKER BIDDLE & SHANLEY LLP
500 Campus Drive
Florham Park, New Jersey 07932
(973) 360-1000

Dated: June 15, 2000

John J. Francis, Jr. (JF 1655)

Attorneys for Plaintiffs
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Gödecke Aktiengesellschaft

Of Counsel:
Robert L. Baechtold (RB 6866)
Hugh C. Barrett (HB 8146)
FITZPATRICK, CELLA, HARPER
& SCINTO
30 Rockefeller Plaza
New York, New York 10112

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